IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
(SHERMAN DIVISION)

ROZLYN ACKERMANN, Individually and as Personal Representative of the Estate of MARTIN LINDSEY ACKERMANN, Deceased, Plaintiff,	§	
v.	§	CASE # 4:05-cv-00084-MHS-DDB
WYETH PHARMACEUTICALS, Defendant.	§	

PLAINTIFF'S OBJECTIONS TO FINDINGS REPORT, AND RECOMMENDATION OF MAGISTRATE JUDGE BUSH REGARDING WYETH'S MOTION FOR SUMMARY JUDGMENT (STATE LAW)

In his November 1, 2006 Report and Recommendation, Magistrate Judge Bush recommends that summary judgment be granted on various state law bases. Pursuant to 28 U.S.C. §636(b)(1)(C), Plaintiff appeals that portion of the Report and Recommendation suggesting that summary judgment is appropriate on Plaintiff's failure to warn theory, based on the "learned intermediary" doctrine.

Introduction and Overview

In *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006), the Magistrate Judge did precisely what the Magistrate Judge is recommending in this case, *i.e.*, he granted summary judgment, for Wyeth, in a pharmaceutical warning's case, based on the learned intermediary doctrine and the testimony of the prescribing physician.[1] The Fifth Circuit reversed.

With respect for the Magistrate Judge, we submit that, if this Court follows his Report and Recommendation, then it would fall into the same error that the court made in *McNeil*.

[1] Actually, if anything, the case at bar is one step farther from summary judgment than *McNeil*. At the Report and Recommendation correctly points out and as discussed *infra*, *McNeil* involved claims of an ***inadequate*** warning, whereas this case involving ***no*** warning about Effexor-induced suicidality at all.

Before proceeding to an analysis of the record, it is perhaps important to eliminate the chaff, *i.e.,* the things that are not in dispute. It is not disputed that there was no warning whatsoever about Effexor-induced suicidality. Therefore, as the Magistrate Judge correctly concluded, there is a "fact issue" on the inadequate warning element of plaintiff's case. R&R at p. 9.[2]

One might query, "if there was no warning, then how can Dr. Sonn be a 'learned' intermediary?" As the Tenth Circuit stated in *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003), "[p]hysicians become learned intermediaries only when they have received adequate warnings **from the drug manufacturer**."

The Magistrate Judge's answer seems to be that it does not matter whether Dr. Sonn is learned, is not, or, in fact, whether he wants to be "learned." In an *ex parte* Declaration that he provided to counsel for Wyeth after his deposition in this case, and, indeed, after our Response was filed to Wyeth's Motion for Summary Judgment,[3] Dr. Sonn seems to declare that, no matter what warning was given, he would still have prescribed Effexor to Marty Ackermann and he might have withheld information from him about the dangers of suicide. Must the Court blithely accept this Declaration, or at least these parts of the Declaration? Or is Dr. Sonn's credibility for the jury to

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[2] *Accord Tobin v. Smithkline Beecham,* Civ. No. 00-CV-0025-Bea (D.Wyo. April 12, 2001)(unpublished opinion attached as Exhibit A to prior Response)("[d]ue to the absence of any arguments as to the adequacy of the warnings regarding [Effexor]-induced violence, manic shifts, psychotic breaks, and suicide this Court finds the adequacy of the warnings a material fact to be decided by the jury.").

Evidence concerning the "inadequacy" of the labeling will necessarily include both (a) the total absence of any warning about an association between Effexor and suicidality, and (b) the misleading nature of the sleight of hand mention of suicide which is in the label. As to the latter, *see* argument in section VI, *infra.*

[3] The procedural irregularity of filing such a Declaration, **not** in support of the original Motion, but as an Exhibit to a **Reply** Brief, should also give the Court extreme pause in any consideration of such.

decide?[4] It all depends upon the facts, as apparent in the summary judgment record, and on the law, as recently explicated by the Fifth Circuit in *McNeil*.

Omitted Findings About Effexor

The Report and Recommendation [hereinafter "R&R] describes at some length Marty Ackermann's use of Celexa and recounts the presence of Celexa in his bloodstream, and the corresponding absence of Effexor (at detectable limits). Although these are not critical to the issue being appealed, they do create a misimpression.

Omitted from the R&R is the juridical fact that Wyeth has chosen not to name its fellow drug company Forest Labs, who makes Celexa, as a "Responsible Third Party" under Texas law.

Also omitted are those record facts, and inferences therefrom, which explain why the Ackermann family believes and the evidence shows that, regardless of what role Celexa may or may not have had, Effexor was also a "substantial factor" or "proximate cause" of Marty's death. No mention is made of the testimony from Marty's widow about how he deteriorated horribly on Effexor. No mention is made of Wyeth's label which suggests that it takes Effexor seven days to clear one's system. (Marty was only off the Effexor five days at the time of his death). No mention is made of the expert testimony that indicates that the physical effects on brain chemistry and behavioral effects of adverse effects persist for some time after a person ceases taking the medication. Nor is there mention of the testimony from Wyeth's own expert witnesses about the pernicious effects of cold turkey withdrawal. A fair appraisal of the evidence condemning Effexor would require recital of these facts of record.

[4] To be sure, Dr. Sonn's credibility will most certainly be at issue given his testimony. Pages 7-8 and exhibits thereto of Plaintiff's Amended Response and Memorandum in Opposition to Wyeth's Motion for Summary Judgment (State Law) [hereinafter "Plaintiff's Response"].

Argument and Authorities

I. *McNEIL* PRECLUDES SUMMARY JUDGMENT

Juxtaposition of the record in this case with that in *McNeil, supra*, demonstrates the inappropriateness of summary judgment on the record before this Court. There are many similarities.

First, there is a similarity regarding the side effects in issue. In *McNeil*, the Court was concerned with "extrapyramidal" side effects ["EPS"]. Akathisia is an extrapyramidal side effect. As the expert report and testimony in the record demonstrate, akathisia is one of the "biologically plausible" pathways via which Effexor increases the risk of suicide for some patients and did so for Martin Ackermann.

Ironically enough, in *McNeil* there was some warning about Reglan-induced EPS: "The clinical pharmacology section of Reglan's FDA-approved label explains that, like other 'dopamine antagonists' such as phenothiazines, Reglan '**may produce** extrapyramidal reactions, although these are comparatively rare.' " 462 F.3d at 366.[5] By contrast, in this case, there is nothing in the Effexor label to suggest that Effexor "may produce" akathisia. That is why this is a "no warnings" case; whereas *McNeil* was an "inadequate" warning's case.

Second, there is a striking similarity regarding the testimony of the prescribing physician. In *McNeil*, as in the case at bar, Wyeth sought summary judgment based on testimony from the prescribing physician that, even if had received a proper warning, it would not have changed his prescribing decision. But, as the Fifth Circuit pointed out, the doctor's equivocation on that point precluded summary judgment:

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[5] The actual injury in *McNeil* was a terrible condition known as "tardive dyskinesia." Ironically, "Reglan's label [also] warned that Reglan may produce tardive dyskinesia." *Id*.

> Admittedly, the physician, in the exercise of professional judgment, can disregard the warnings or contraindications provided by the manufacturer. But then he does so at his own risk, and most physicians are likely reluctant to do so absent more concrete evidence about the benefits of long-term use, evidence that is absent in this case. Even Dr. Wilkinson, who initially indicated that he would not have changed his long-term prescription of Reglan even if he had read the studies now cited by McNeil, acknowledged that he would not have prescribed Reglan for more than twelve weeks had Wyeth provided a contraindication on Reglan's label.

Id. at 372. As noted below, Dr. Sonn has testified on the one hand, that he would still do the same thing, and, yet, on the other, that he heeds black box or other prominent warnings. Indeed, even his *ex parte* Declaration plainly states that "if there were a legal requirement that I communicate the warning set forth in paragraph 1 directly to a patient, I would comply with that requirement." In this case, as in *McNeil*, "[the prescribing doctor] gave conflicting testimony. . . . Therefore, McNeil has raised a genuine issue of fact as to whether Wilkinson would have prescribed the drug had the label's warning been adequate." *Id*. In this case, as in *McNeil*, summary judgment may not rest on so shaky a foundation.

Finally, as the *McNeil* court explained, "[t]he doctrine of the 'learned intermediary' presupposes that the physician will act as an intermediary. This function **includes discussing the cost-benefit ratio with the patient** if necessary." *Id*. at 373. The R&R suggests that summary judgment is appropriate because Dr. Sonn states that he would not have told Marty about the risk of suicide, unless there was a "legal requirement" that he do so. This discussion is under the heading of whether the inadequate (or wholly missing) warnings could be a "producing cause of Ackermann's death." R&R at p.9.

McNeil points out that such a requirement is implicit in the "learned intermediary" doctrine itself. And it explains that, contrary to the recommendation of the Magistrate Judge, "the inadequate labeling **could** be a 'producing' cause of the injury, because it effectively **sabotages the function**

of the intermediary." *Id.* (emphasis added). In the companion footnote #6, the Court elaborated that (a) the duty to warn encompasses an obligation to make sure that the warning reaches those who are "endangered by the use of its products," (b) that ordinarily a drug company can expect the "learned intermediary" to pass on that warning, but, critically, (c) "this reliance seems less reasonable where the learned intermediary fails to pass necessary information to the patient because the manufacturer has understated the degree of risk." In the case at bar, Wyeth has not "understated the degree of risk" concerning Effexor-induced suicidality. It has ignored it altogether. It "sabotaged" the intermediary.

Significantly, in *McNiel* there was testimony that, if the doctor had passed on the warnings, then the patient would not have taken the medication. There is similar testimony here. Although Marty Ackermann is dead, his widow Rozlyn went with him to see Dr. Sonn and has testified that if they had been told about the associated risks of suicide with Effexor, she and her husband "would not have just walked out the door, but put on my sneakers and run as fast as I can . . . down the highway back to my home with my husband. We wouldn't have touched it with a 10-foot boughed [sic]." Exhibit E to Wyeth's Memorandum in Support of Defendant's Motion for Summary Judgment (State Law), Rozlyn Ackermann deposition at pp. 91:7-92:7.

II. DR. SONN'S *EX PARTE* DECLARATION FAILS TO REBUT THE COMMENT *j* "HEEDING PRESUMPTION"

The linchpin of Wyeth's Motion and the Magistrate Judge's Recommendation is the August 11, 2006 Declaration from Dr. Sonn. Wyeth's argument, which the Magistrate Judge bought, is that, even if Wyeth had communicated a "prominent warning" and even if they had "brought home" that warning to him, he would not have done anything different. The argument and evidence do not stand up to scrutiny.

We begin, of course, with the legal presumption. Under comment *j* to Restatement section 402A, a product manufacturer benefits from a presumption that their legally adequate warning would and should have been heeded by the user of the product. *Magro v. Ragsdale Brothers*, 721 S.W.2d 832, 834 (Tex. 1986). But in Texas, as in a number of other states, the courts have construed comment *j* to provide a corollary presumption in favor of the plaintiff in a "no warning" case like this. *Reyes v. Wyeth Laboratories,* 498 F.2d 1264, 1281 (5th Cir.). It is usually labeled as a "heeding presumption," and, in operation, the law presumes that the consumer, or, in the case of a pharmaceutical product, the "learned intermediary,"[6] would have heeded an adequate warning IF such a warning had been given.

Summary judgment for a defendant can still be appropriate if there is clear and unequivocal proof that the consumer would not have heeded such a warning. It might be appropriate in a learned intermediary case if there was such evidence from the prescribing doctor, although *McNeil's* discussion of the nature of that relationship and the "sabotaging" of same casts considerable doubt on that. But the Court need not go to this issue in this case, because Dr. Sonn's Declaration states quite clearly that "I **would have** considered or **heeded** it just as I consider or heed any warning."

His deposition testimony demonstrates the degree to which he heeds other black box warnings. Dr. Sonn admitted that, even though he has never had a patient who became psychotic

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[6] No Texas state court has either accepted or rejected the "heeding presumption" in a "learned intermediary" context. However, the *Erie* predictions of federal district courts have split on the issue with the Southern District going one way, and the Northern another. *Compare Anderson v. Sandoz Pharmaceuticals Corp.*, 77 F.Supp.2d 804 (S.D.Tex. 1999), with *Koenig v. The Purdue Pharma Co.,* 2006 WL 1489250 (N.D.Tex. May 25, 2006). Because the heeding presumption is perfectly consistent with the traditional rationale for strict liability, the best *Erie* prediction that this Court can make is that the Texas courts will embrace it, even in a learned intermediary context.

This issue was fully briefed, but completely ignored, in the R&R.

on Ritalin, he still warns his patients about that risk.[7] This is extremely germane in this case because one of the biologically plausible pathways or "antecedent" conditions triggered by Effexor and which, in turn, trigger suicidality, is drug-induced psychosis. It is, in fact, the precise mechanism of action which is most accountable for Martin Ackermann's death. Exhibit D to Plaintiff's Response at pp. 290, 324 (excerpts from deposition of Plaintiff's expert, Dr. David Healy).

In the context of a summary judgment motion, all inferences are to be resolved against the movant. There is a clear and strong inference that, if Dr. Sonn heeded one drug maker's warning about drug-induced psychosis, he would, likewise, have heeded a similar warning from Wyeth about Effexor-induced psychosis. This, in and of itself precludes summary judgment.

Additionally, part of Dr. Sonn's "heeding" is that he also regularly passes the warnings on to his patients. Specifically, Dr. Sonn testified that what he *usually* does is ". . . hand them a box that has this in it, has some directions inside."[8] He said that before prescribing a drug he would review the *Physician's Desk Reference*, "But I would be primarily interested in the side effects, the warnings."[9] For example, he testified that he prescribes Ritalin from time to time. As noted above, Ritalin has a black box warning that includes psychosis. Even though he's never had a patient become psychotic while taking Ritalin, he still warns them about this side effect because it's within

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[7] As *McNeil* itself illustrates, Plaintiff still does not always bear the burden of proving that, with an adequate warning, the prescribing physician would have refused to prescribe the drug. The law in Texas is that a product maker must not only provide warnings about the risks inherent in their product, but also instructions for ways to ameliorate that risk. *See* Texas PJC § 71.5. To that end, there are many ways that the risk of Effexor-induced suicidality could be ameliorated other than non-prescription. They include (a) careful monitoring, (b) concomitant antidotes for the SSRI-induced precursors to suicidality, (c) tapering of the drug, and (d) words of caution to the patient and family. Such instructions are embodied in the German Prozac warnings that were at issue in *Woulfe v. Eli Lilly*, 956 F.Supp. 1478, 1485 (E.D.Okla. 1997). Notably, this is exactly what Dr. Sonn does with his Ritalin patients.

[8] Sonn deposition, p. 22.

[9] Sonn deposition, p. 42.

the black box.[10] He also stated that, "I mean, if–if it's black boxed and indicated, then you would do it."[11]

In his deposition, this 72-year-old semi-retired psychiatrist, who keeps no records whatsoever on his patients, testified that if required to do so by law, he would give a black box warning. His Declaration echoes the same refrain: "If there were a legal requirement that I communicate the warning set forth in paragraph 1 directly to a patient, I would comply with that requirement." Obviously there is such a "legal requirement" under Texas law. It is called "informed consent." *Barclay v. Campbell,* 704 S.W.2d 8, 10 -11 (Tex. 1986). Also, as *McNiel* itself makes clear, "[t]he doctrine of the 'learned intermediary' presupposes that the physician will act as an intermediary. This function includes discussing the cost-benefit ratio with the patient if necessary." 462 F.3d at 363.

There is certainly a reasonable inference that any physician practicing medicine in Texas – particularly one who has practiced as long as Dr. Sonn – would know that he has a legal obligation to inform his patient, fully and reasonably, about potentially lethal side effects of a medication before dispensing it to him. That inference, coupled with Dr. Sonn's equivocation, precludes summary judgment in this case.

Finally, although the Magistrate Judge suggests that, even if a fully adequate warning had been provided, Dr. Sonn would simply not have changed his prescribing decision. There is certainly testimony from which one could make that conclusion. But again, there is contradictory testimony

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[10] Sonn deposition, p. 184.

[11] Sonn deposition, p. 125.

that requires resolution by the trier of fact.[12] In his deposition, Dr. Sonn admitted that, with the information he now has about Effexor and suicidality, "I would–it would have to be approached differently now. And on the basis of this experience, at my age, I don't know whether I might not **refer somebody to another physician**."[13] Thus, even if the plaintiff must prove that this particular physician would not have prescribed the medication in question, which we continue to dispute, the reasonable inferences from the testimony establish a triable case. If Dr. Sonn referred Marty Ackermann "to another physician," then, obviously, he would not have prescribed any medication at all for Mr. Ackermann.

III. WYETH HAS ADDUCED NO PROOF THAT A "REASONABLY PRUDENT PHYSICIAN" WOULD NOT HEED A WARNING

A corollary of the heeding presumption in many states is that, even if it does not switch the burden of proof entirely, the focal point for rebutting the presumption is not the subjective state of mind of the actual prescribing physician, but rather the "reasonably objective" independent physician. In two Mississippi diversity cases, the Fifth Circuit has stated the test in alternative terms:

> To satisfy the burden of establishing warning causation, a plaintiff may introduce **either** objective evidence of how a reasonable physician would have responded to an adequate warning, **or** subjective evidence of how the treating physician would have responded.

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[12] A common denominator in those cases in which summary judgment has been granted and/or sustained based on the prescribing physician's testimony, is a lack of equivocation. *E.g., Garside v. Osco Drug, Inc.*, 976 F.2d 77, 82 (1st Cir.1992)("the physician's testimony [must] show unequivocally that s/he knew at the relevant time all the information which would have been included in a proper warning.")' *In re Norplant Contraceptive Products Liability Litigation,* 215 F.Supp.2d 795 (E.D.Tex., 2002)("[a]ll five of the prescribing physicians testified unequivocally . . .").

Dr. Sonn's obvious equivocation, even in his Wyeth drafted Declaration, precludes summary judgment based on his testimony.

[13] Sonn deposition, p. 126.

Thomas v. Hoffman-LaRoche, Inc. 949 F.2d 806, 812 (5th Cir. 1992)(emphasis added). *Accord Hermes v. Pfizer, Inc.*, 848 F.2d 66, 69-70 (5th Cir.1988). *See also Cunningham v. Charles Pfizer & Co., Inc.,* 532 P.2d 1377 (Okla. 1975).

Significantly, Texas Pattern Jury Instructions concerning marketing defects in products liability cases demonstrate that Texas follows the "objective" standard:

> "Adequate" warnings and instructions mean warnings and instructions given in a form that could reasonably be expected to catch the attention of a **reasonably prudent person** in the circumstances . . . the content of the warnings and instructions must be comprehensible to the **average user** . . . to the mind of a **reasonably prudent person.**

Tex PJC §71.5 (emphasis added). Obviously, in a prescription drug case, "reasonably prudent physician" would be substituted in lieu of "reasonably prudent person." This is a **reasonably prudent** physician – and it is not Dr. Sonn, either representatively or otherwise.

Because Wyeth has come forward with no proof that any reasonably objective physician would have ignored a clear warning from Wyeth about Effexor-induced suicidality, summary judgment is inappropriate.

IV. SUMMARY JUDGMENT CANNOT BE SUSTAINED ON THE BASIS OF A WITNESS WHOSE CREDIBILITY IS IN SEVERE QUESTION

A. Dr. Sonn Is Clearly Biased Against the Ackermann Family. In the Prozac/suicide case of *Woulfe,* summary judgment was granted because there was no evidence in the summary judgment record which, in the judge's opinion, raised a question about the prescribing physician's credibility:

> "The weight to be afforded such affidavit or testimony, however, depends on the substance of the evidence as well as the credibility and reliability of the treating physician himself. In the instant case, Plaintiff has offered absolutely nothing to call into question either the substance of Newey's affidavit or his credibility with respect to the statements he makes."

In this case, by contrast, there is a wealth of evidence which calls Dr. Sonn's credibility into question. It is abundantly clear from his deposition that Dr. Sonn is extremely biased against plaintiffs in general and this family in particular. When Dr. Sonn received a request for his records on Martin Ackermann, he reacted by notifying his malpractice carrier and obtaining the services of an attorney.[14] When reminded that no allegations had been made against him in this case, Dr. Sonn stated, "I still–it still doesn't make me like this process any more."[15] And then, quite tellingly, he added a gratuitous *ad hominem* attack on the Ackermann family's counsel:

> "I'm generally not a fan of Plaintiff attorneys who bring these kind of suits."[16]

This demonstrable bias creates questions of credibility, which must be decided by the jury.

There is also ample evidence of coaching or cooperation between Dr. Sonn and Wyeth's counsel. Before his deposition, Dr. Sonn had never met with Mrs. Ackermann's attorneys–but he had considerable communication with Wyeth's. On two occasions, he'd spoken with defense counsel, and he met with them for an hour before his deposition.[17] Additionally, during multiple breaks during his deposition he consulted with Wyeth's counsel.[18] And, of course, as noted above, he provided counsel for Wyeth with the very Declaration upon which the Magistrate Judge's Report and Recommendation is founded, on an *ex parte* basis at that, and only after the Plaintiff had filed her Response to Wyeth's Motion for Summary Judgment.

Bias? Plenty of it. A question of credibility for the jury? Truly.

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[14] Sonn deposition, pp. 75,76.

[15] Sonn deposition, p. 182.

[16] Sonn deposition, p. 162.

[17] Sonn deposition, pp. 58, 59.

[18] Sonn deposition, p. 160.

B. Dr. Sonn Is Clearly Biased in Favor of Wyeth, Which Supplies Him with Free Effexor to Self-Medicate His "Lifetime" Condition. It is also clear that Dr. Sonn has a very good reason to be prejudiced in favor of Wyeth. Wyeth supplies him with drugs for his own personal use. He doesn't have to pay a dime for them. He testified as follows:

> I had an episode of depression in 1997 and I take Effexor myself and so I use the samples."[19] . . . I take 225 milligrams a day. I've been taking that for more than five years and I think it's a lifetime thing for me.[20]

Cases are legion which say that a Court may not pass judgment on a witness's credibility in the context of a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). Do these record facts establish a basis for questioning Dr. Sonn's credibility? Obviously. Is one of the inferences, which must be resolved **against** Wyeth as summary judgment movant, that Dr. Sonn's "lifetime" dependence on Effexor, and his free supply of same from Wyeth itself, undermine his credibility? Clearly so.

With testimony like this directly from Dr. Sonn himself, it is evident that this man's testimony does not, and cannot, provide Wyeth with a sufficient basis for summary judgment. Rather, in this case, as in *McNeil* and *Tobin, supra*, his credibility presents a classic question for the jury. This is particularly so in light of the fact that all inferences must be resolved in favor of the non-movant. There is a reasonable inference that a doctor who is patently prejudiced against his own patient's family and counsel, and who self-medicates with free drugs from a pharmaceutical company is not likely to bite the hand that feeds him, or criticize the very drugs that he himself takes

[19] Sonn deposition, p. 9.

[20] Sonn deposition, p. 19.

at their largesse. Because the Report and Recommendation completely ignores these critical record facts, summary judgment is inappropriate.

C. Dr. Sonn's Lack of Records and Strange Recollection Also Create Jury Questions Concerning His Credibility. Dr. Sonn saw Martin Ackermann in January of 2002. After just a few visits, Marty fired him. Dr. Sonn has no notes of his sessions with Marty. He keeps no records on any of his patients.[21] Dr. Sonn estimated that he sees patients at the rate of 800 office visits per year. His deposition was taken nearly four years—or 3,200 office visits later—and he had no records to refresh his memory about Martin Ackermann.[22] Yet he testified for hours about Marty's condition, conversations between him and the patient, conversations between him and the referring partner from Gardere, Wynne & Sewell, side effects of the medication that Marty had been experiencing, symptoms he had, symptoms he *didn't* have, etc. All of this about two office visits, four years, and 3,200 patients later.

Incredible.

V. THE REPORT AND RECOMMENDATION ALSO IGNORES THE "OVERPROMOTION" EXCEPTION TO THE LEARNED INTERMEDIARY RULE

Plaintiff's Response provided the Magistrate Judge with an additional, altogether different, basis for declining to rely on the "learned intermediary" doctrine for summary judgment in this case. It was ignored.

The learned intermediary doctrine is a common law affirmative defense. The courts which have accepted, or created, that defense have likewise recognized several exceptions to the defense. One of these is "overpromotion." *Vitanza v. The Upjohn Co.*, 778 A.2d 829, 847 (Conn. 2001),

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[21] Sonn deposition, p. 169.

[22] Sonn deposition, p. 177.

citing *Proctor v. Davis*, 291 Ill. App. 3d 265, 279-84, 682 N.E.2d 1203, 225 Ill. Dec. 127, cert. denied, 175 Ill. 2d 553, 689 N.E.2d 1146, 228 Ill. Dec. 725 (1997). Although no Texas court, or even federal court applying Texas law, has decided the issue, the best *Erie* prediction is that the Texas courts will follow the common law majority and embrace this exception as well.

The summary judgment record contains ample proof that Wyeth used promotional campaigns for Effexor which the FDA itself labeled as "false and misleading."[23] Surely this is evidence of "overpromotion."

If Texas follows the common law exceptions to this common law defense, then this evidence would preclude summary judgment on the basis of the "learned intermediary" doctrine.

VI. THE "MISLEADING" REFERENCE TO SUICIDE IN THE EFFEXOR LABEL ALSO MILITATES AGAINST SUMMARY JUDGMENT

As the Report and Recommendation correctly reflect, the "only mention of a 'risk of suicide' contained in the [package] insert" for Effexor is one which suggests that the "possibility of a suicide attempt is inherent in depression." R&R at p.9. There is nothing which suggests that the medication could be part of the problem instead of part of a cure.[24] This is obviously patently misleading.

After the summary judgment motion was fully briefed before the Magistrate Judge, the Fifth Circuit handed down *McNeil*. In that opinion the Fifth Circuit squarely held that "'if the warning to the intermediary is inadequate **or misleading**, the manufacturer remains liable for injuries sustained

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[23] There is considerable irony in this. In their separate motion for summary judgment on preemption grounds, Wyeth argues that, if they had tried to issue a warning about the association between Effexor and adult suicidality before Marty Ackermann took the drug, then the FDA might have labeled it as "false and misleading." And, yet, Wyeth takes a ho hum attitude about the fact that the FDA actually did label Wyeth's promotional material for Effexor as "false and misleading."

[24] There is a ten penny medical word for the phenomenon of maladies which are caused by medical treatment. It is "iatragenic." One of the classic articles concerning iatragenic suicide, triggered by SSRI drugs was written by a defense expert. It begins with a lamenting quotation: "From making the cure more grievous than the disease, Good Lord deliver us." Exhibit V to Plaintiff's Motion to Exclude Certain Testimony From Defense Experts Schatzberg and Peck and Wyeth's In-House Experts.

by the ultimate user'" and that, in the face of evidence of a misleading label, summary judgment is inappropriate. *McNeil*, 462 F.3d at 368 (emphasis added, citations omitted).

This, too, is yet another reason for denying summary judgment in this case.

CONCLUSION

McNeil lights the Court's path. In this case, as in that one, Wyeth's failure to provide adequate warnings, and, in fact, providing "misleading" labeling concerning the risk of suicide, has "sabotaged the intermediary."

Moreover, the recommended summary judgment in this case necessarily rests on a witness whose credibility is in serious question, by virtue of the fact that Wyeth provides him with free Effexor for his personal use, and whose testimony is riddled with inconsistency and equivocation.

Finally, because the Magistrate Judge ignored both the "heeding presumption" and "overpromotion" issues, summary judgment should also not be granted.

Respectfully submitted,

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Certificate of Service

I certify that on this 3rd day of November, 2006, Plaintiff's Objections to Findings Report and Recommendation of Magistrate Judge Bush Regarding Wyeth's Motion for Summary Judgment (State Law) has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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